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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/039,952	10/24/2001	J. David Rozzell JR.	47418/KMO/B583	1571

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EXAMINER

GITOMER, RALPH J

ART UNIT PAPER NUMBER

1651

DATE MAILED: 04/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/039,952

Applicant(s)

ROZZELL, J. DAVID

Examiner

Ralph Gitomer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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The amendment received 3/29/05 has been entered and claims 18-24 are currently pending in this application. In view of the amendments to the claims and arguments presented, all rejections of record are hereby withdrawn. However, note the new rejections below. New references are applied, hence this Office Action is made non-final..

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of each of Yamada and Liu in view of each of Engel and Yan.

The claims are directed to a method for producing an amine from a target ketone with an enzyme that has been mutated from an existing enzyme. How the mutation is achieved or the result of the mutation is not claimed.

Yamada (US 2002/0192786 A1) entitled "Producing Optically Active Amino Compounds" teaches in the abstract, enzymes that act on a ketone compound in the presence of an amino group acceptor. See Table 3 on page 5. The method of isolating various enzymes is taught.

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Liu (6,365,380) entitled "Method for Stereoselectively Inverting A Chiral Center of A Chemical Compound Using an Enzyme and A Metal Catalyst" teaches in column 2 lines 35-43, amino acid transaminases where keto compounds are converted to amines. In claim 1 amino acid dehydrogenase is shown.

The claims differ from the above references in that they state the enzyme is mutated.

Engel (5,798,234) entitled "Method For the Directed Modification of Enzymes, Modified Enzymes And Their Use" teaches in the abstract, modifying enzymes. In column 1 amino acid dehydrogenases were screened. In column 3 lines 44-55, modified amino acid dehydrogenases from mutants are shown. Aspartate and glutamine are substrates. In columns 6-7 a table compares wild type to mutant enzymes where the mutants have a higher activity.

Yan (US 2003/0138930 A1) entitled "Isolated Human Dehydrogenase Proteins, Nucleic Acid Molecules Encoding These Human Dehydrogenase Proteins, and Uses Thereof" teaches in paragraph 49, generating mutants of dehydrogenases. See also paragraphs 52 and 75.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a mutated enzyme in the methods taught by the above primary references because the secondary references teach methods of making and using mutated enzymes. One of skill in this art finds it desirable to select for enzymes of specific activities under specific conditions by either selecting known enzymes or producing mutated enzymes as taught by each of the secondary references. No

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method of mutating or result of such mutating is claimed. No activity or conditions of the resulting enzyme is claimed.

Claim 23 further differs from the above cited references in that it recites a number of types of enzymes.

No novelty is seen in any of the enzymes of claim 23. Various classes of transaminases are taught by the above references which would encompass some of those claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

Claim 18 is directed to a mutated enzyme but in what fashion or result the mutation is made is not seen in comparison with a not mutated enzyme. Claim 21 is not understood where one would not likely provide an enzyme that does not exist. Such enzymes likely exist in an organism. Further, it is directed to mutating an enzyme but does not set forth how it is mutated.

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Applicant's arguments filed 3/29/05 have been fully considered but they are not persuasive.

Applicant argues that the claims are definite and mutation techniques are taught in the specification. There is no legal requirement to specify how the enzyme is mutated.

It is the examiner's position that one would not know if some enzyme has been mutated or not in some fashion, therefore one would not know if the enzyme is encompassed by the claims. One could say all naturally occurring enzymes are to some degree the result of some sort of mutation and certainly all non-naturally occurring enzymes would be mutated.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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